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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

FEDERAL TRADE COMMISSION,	:	
	:	Civil No.
Plaintiff,	:	
vs.	:	
CHRISTOPHER ENTERPRISES, INC.,	:	Stipulated Order for Preliminary
a corporation, and	:	Injunction
NORMAN BACALLA and RUTH	:	
CHRISTOPHER BACALLA, individually	:	
and as officers of the corporation,	:	
Defendants	:	
	:	

Plaintiff, the Federal Trade Commission (“FTC” or “Commission”), filed a Complaint for permanent injunction and other relief against Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla, pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b). Plaintiff FTC filed its complaint to secure a permanent injunction, preliminary injunction, and other equitable relief, against Defendants for their deceptive acts or practices and false advertisements for foods, drugs, devices, services or cosmetics in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The Commission and Defendants have agreed to the entry of a Stipulated Order for Preliminary Injunction (“Order”) against Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla, with the following terms:

FINDINGS

1. This Court has jurisdiction over the subject matter of this case and jurisdiction over all parties. Venue in the District of Utah is proper.
2. The Complaint states a claim upon which relief can be granted, and the Commission has authority to seek the relief it has requested.
3. Defendants have been served with the Summons and Complaint.
4. Entry of this Order is in the public interest.

DEFINITIONS

For the purposes of this Order, the following definitions shall apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using

procedures generally accepted in the profession to yield accurate and reliable results.

2. “Defendants” means Christopher Enterprises, Inc., Norman Bacalla, Ruth Christopher Bacalla, and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division or other device.

3. “Food” and “drug” shall mean “food” and “drug” as defined in Section 15 of the FTC Act, 15 U.S.C. § 55(b)-(c).

4. “Comfrey product” shall mean any product consisting of, containing, or including as an ingredient any of the following plants, any part of the following plants, or any extract or derivative of the following plants: *Symphytum officinale* (also known as common comfrey), *Symphytum asperum* (also known as prickly comfrey), or *Symphytum x uplandicum* (also known as Russian comfrey).

5. “Clearly and prominently” shall mean as follows:

a. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the advertisement. Provided, however, that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. Provided, further, that in any advertisement communicated through interactive media which is presented predominantly through visual or audio means, the disclosure may be made through the same means in which the

advertisement is predominantly presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The visual disclosure shall be of a size and shade, with a degree of contrast to the background against which it appears, and shall appear on the screen for a duration and in a location, sufficiently noticeable for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media, the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

b. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multi-page documents, the disclosure shall appear on the cover or first page.

c. On a product label, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears. Provided, however, if a disclosure on a bottle label or package label is made in a location other than the principal display panel, the bottle label or package label shall include the statement, “See important safety warning on [insert disclosure location]” as follows: (a) in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it; (b) in print that contrasts with the background against which it appears; and (c) within a border that is a color or shade that contrasts with the background against which it appears. Provided further, that in a multi-page insert, the disclosure shall appear

on the cover page or first page.

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

6. A requirement that any Defendant communicate with the Commission shall mean that the Defendant shall send the necessary information via first-class mail, costs prepaid, to the Regional Director, Federal Trade Commission, Southwest Region, 1999 Bryan Street, Suite 2150, Dallas, TX 75201. Attn: FTC v. Christopher Enterprises, Inc., et al. (D. Utah).

7. The term “including” in this Order shall mean “without limitation.”

8. The terms “and” and “or” in this Order shall be construed conjunctively or disjunctively as necessary to make the applicable phrase or sentence inclusive rather than exclusive.

I. CONDUCT PROHIBITIONS

A. **IT IS THEREFORE ORDERED** that, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any comfrey product, Defendants and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division or other device, are preliminarily restrained and enjoined:

1. From marketing such product for ingestion, for use as a suppository, or for external use on open wounds; and
2. From failing to make the following disclosure, clearly and prominently, in any advertisement, promotional material, package label, and package insert for any

comfrey product marketed for other external use:

WARNING: External Use Only. Consuming this product can cause serious liver damage. This product contains comfrey. Comfrey contains pyrrolizidine alkaloids, which may cause serious illness or death. This product should not be taken orally, used as a suppository, or applied to broken skin. For further information contact the Food and Drug Administration: <http://vm.cfsan.fda.gov>

unless Defendants possess competent and reliable scientific evidence conclusively demonstrating that the product is free of pyrrolizidine alkaloids and safe for such uses. Provided, however, that in the event the Food and Drug Administration issues a rule or regulation that requires a warning or a disclosure on the labeling of products containing comfrey, Defendants may substitute that warning for the disclosure required under this Paragraph.

B. IT IS FURTHER ORDERED that, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any comfrey product, Defendants and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division or other device, are preliminarily restrained and enjoined from representing in any manner, expressly or by implication, that:

1. Such product is effective in the prevention, mitigation, treatment or cure of asthma, arthritis, broken bones, bronchitis, cancer, “charlie horses,” colds, coughs, cramps, curvature of the spine, emphysema, headache, herpes simplex, infection, insomnia, lung congestion, multiple sclerosis, muscular dystrophy, osteoporosis, paralysis, polio, prolapsed bowel and uterus, pyorrhea, rheumatism, sore throats,

spinal cancer, stroke, thrush, toothache, tuberculosis, varicose veins, or yeast infections;

2. Such product is effective in supplying all calcium needs, including all calcium needs of a developing fetus, or in restoring teeth; or
3. Such product is safe and effective for the uses for which it is sold;

unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

C. **IT IS FURTHER ORDERED** that, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, drug, dietary supplement, or other health-related product or service, Defendants and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division or other device, are preliminarily restrained and enjoined from making any representation in any manner, expressly or by implication, about the safety, health benefits, performance, or efficacy of such product or service, unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II. FOOD AND DRUG REGULATIONS

A. **IT IS FURTHER ORDERED** that nothing in this Order shall prohibit Defendants from making any representation for any product that is specifically permitted in the labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

B. **IT IS FURTHER ORDERED** that nothing in this Order shall prohibit Defendants from making any representation for any drug that is permitted in the labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration or under any new drug application approved by the Food and Drug Administration.

III. RECORD KEEPING

IT IS FURTHER ORDERED that Defendants are preliminarily restrained and enjoined from failing to preserve and maintain with respect to any representation covered by this Order:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession, custody, or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

IV. DISTRIBUTION OF ORDER BY DEFENDANTS

IT IS FURTHER ORDERED that Defendants shall immediately provide a copy of this Order to each of their affiliates, subsidiaries, divisions, successors, assigns, officers, directors, and managers, employees, independent contractors, agents, and representatives having responsibilities with respect to the subject matter of this Order, and shall, within ten (10) days from the date of entry of this Order, provide Plaintiff with a sworn statement describing the manner in which Defendants have complied with this provision of the Order, which statement shall include the names and addresses of each person and entity that received a copy of the Order.

V. NOTIFICATION TO DISTRIBUTORS

IT IS FURTHER ORDERED that:

- A. Defendants shall not disseminate to any distributor any material containing any representation prohibited by this Order.
- B. Defendants shall not, directly or indirectly, authorize any distributor to make any representation prohibited by this Order.
- C. Within ten (10) days after entry of this Order, Defendants shall send by first class mail a notice, in the form shown on Appendix A, to each distributor with whom Defendants have done business since January 1, 1998, to the extent that such distributor is known to Defendants through a diligent search of their records, including but not limited to computer files, sales records, and inventory lists. The mailing shall not include any other documents. Defendants shall require each distributor to execute and return the original of the letter as a condition of remaining or once again becoming a distributor for Defendants.
- D. Defendants shall institute a reasonable program of surveillance adequate to reveal whether any of Defendants' distributors are disseminating advertisements or promotional materials or making any oral statement that contain any representation prohibited by this Order.
- E. Defendants shall terminate all sales to any of any food, drug, device service, or dietary supplement to any distributor who is using or disseminating any advertisement or promotional material or making any oral statement that contains any representation prohibited by this Order, once Defendants know or should know that the distributor is or has been engaged in such conduct. Defendants shall immediately provide, by certified mail, all relevant information, including name, address, and telephone number of the distributor at issue, the nature of the

violation, and any relevant materials used or disseminated, to the Regional Director, Federal Trade Commission, Southwest Region, 1999 Bryan Street, Suite 2150, Dallas, TX 75201. Attn: FTC v. Christopher Enterprises, Inc., et al. (D. Utah).

VI. COMPLETION OF FINANCIAL STATEMENTS

IT IS FURTHER ORDERED that, to the extent not previously provided to Plaintiff, each Defendant, not later than three (3) business days after entry of this Order, shall provide counsel for the Commission with a completed individual or corporate financial statement, as appropriate, on the forms attached to this Order as Attachments B and C. Defendants shall attach to these completed financial statements copies of all state and federal income and property tax returns, with attachments and schedules, as called for by the financial statements.

SO ORDERED:

DATED: _____

UNITED STATES DISTRICT JUDGE

SO STIPULATED:

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APPENDIX A

FIRST CLASS MAIL

[To be printed on Defendant's letterhead]

[date]

Dear [distributor's name]:

This letter is to inform you that our company recently entered into an stipulated preliminary injunction with the Federal Trade Commission regarding our advertising for certain products containing the herb comfrey, which the company has sold both directly to consumers and through resellers. As a part of the preliminary injunction, we must make sure that you comply with the preliminary injunction, which was entered by the United States District Court for the District of Utah on _____ (date). Among other things, the preliminary injunction requires us to notify all purchasers of serious hazards that may attend use of comfrey if it is taken internally by oral ingestion, used as a suppository, or applied to broken skin, and to instruct resellers to stop using advertising or promotional materials that promote such uses of any product containing comfrey or that make any other representation prohibited by the preliminary injunction. Importantly, the preliminary injunction requires us to monitor our resellers and terminate all sales to any reseller who disseminates advertising or promotional materials that expressly or by implication make any claims about our comfrey products that we may not make pursuant to the order.

The FTC complaint alleged that the company engaged in deceptive advertising of its comfrey products, and the preliminary injunction imposes various requirements in connection with its past and future advertising of these and other products. According to the FTC complaint, our advertising materials claimed, expressly or by implication, that comfrey products may safely be used as oral preparations and suppositories and may be applied to open wounds. The complaint challenges these claims as false and unsubstantiated. In particular, the FTC notes that comfrey contains pyrrolizidine alkaloids which have been linked to serious illness, occasionally leading to death. In addition, the complaint charged that the company made unsubstantiated claims that comfrey products are effective in preventing, treating, relieving, and curing certain illnesses and medical conditions.

The preliminary injunction prohibits us from making any of the challenged claims unless we have competent and reliable scientific evidence to support them. In addition, it prohibits us from marketing comfrey products for use internally, by ingestion, as a suppository or applied to broken skin and it requires us to make the following safety disclosure, clearly and prominently, in connection with the promotion and marketing of comfrey products:

WARNING: External Use Only. Consuming this product can cause serious liver damage. This product contains comfrey. Comfrey contains pyrrolizidine alkaloids,

which may cause serious illness or death. This product should not be taken orally, used as a suppository, or applied to broken skin. For further information contact the Food and Drug Administration: <http://vm.cfsan.fda.gov>

The preliminary injunction prohibits us from making unsubstantiated claims for any food, drug, dietary supplement, or health-related product or service. In addition, we are required to monitor and terminate all sales to resellers making prohibited claims for our comfrey products.

We request your assistance by asking you NOT to use, rely on, or distribute any advertising or promotional materials containing unsubstantiated claims and NOT to make unsubstantiated oral representations. If you have customers who buy the products for distribution or resale, please also notify them to do the same. If you or your customers continue to use prohibited materials or make false or unsubstantiated representations, we are required by the preliminary injunction to stop doing business with you and to inform the FTC of your activities.

Although we do not admit that the FTC's allegations are true, we have agreed to send this letter as a part of the preliminary injunction.

Please sign, date, and return this letter to [Defendant] at the above address, acknowledging your agreement to the terms set forth herein.

Thank you very much for your assistance,

[Defendant's signature]

ACKNOWLEDGMENT AND AGREEMENT

The undersigned acknowledges receipt of this letter and hereby agrees to its terms and conditions.

Date

Signature